K123761

A Dreve Company

510(k) Summary

MAR 0 1 2013

- **Submitter** .... Innovation MediTech GmbH
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  Germany
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- **Date Prepared** .... December 1, 2012

- **Trade/Device Name:** Enamic® Stains
- **Common Name:** Stain and Glaze
- **Classification Name:** Coating, Filling Material, Resin
- **Class II per 21 CFR 872.3310**
- **Product Code:** EBD

Predicate Devices: 510(k)982259 Chroma Zone Color Stain
510(k)024046 Discover XT/ Tescera Glazing Resin

Device Description

The Vita Enamic® Stains are color intensive resins used for shade characterization of the surfaces of hybrid ceramic restorations made from Vita Enamic The shades are supplied in powder form. This powder is mixed with a liquid and applied in a very thin layer to an Enamic restoration to adjust the shade or create characteristics found in natural teeth, such as cracks, stains or white spots. The painted restoration is then sealed with a clear light-curing glaze to create a smooth and glossy finish that is resistant to abrasion. The Stains are a dual curing system of auto and light polymerization that is prepared outside the mouth.

Statement of Intended Use:

Vita Enamic® Stains are indicated for shade customization and characterization of the surface of dental restorations made of hybrid ceramic-resin and resin materials.

Substantial Equivalence

Information provided in this application shows that the product is substantially equivalent to the predicate devices in intended use, materials, application, and polymerization methods.

Technological Characteristics

Design

The Vita Enamic Stains are similar in design to the predicates listed above. Like the predicates, the Enamic Stains are intended to be applied in-vitro for the purpose of manipulating the shade or adding characteristics to a dental restoration to ensure proper matching of the patient's natural teeth.

Unlike the predicates, Vita Enamic Stains are not offered in paste form, but in separated powder and liquid form. This allows the user full control of the stain intensity by the measure of liquid used with the powder. The Enamic Stains also include a glazing liquid to seal in the stains which protect the stain from wearing off and create a smooth, glossy surface to the finished device.

Material

Like the predicate materials, the Vita Enamic is based on multifunctional acrylates. An assessment of the biocompatibility according to FDA Recognized Consensus Standard ISO 10993 is included in this application. We conclude, as a result of this assessment/testing, that the device is safe for its intended use.

Summary of Non-Clinical Performance Data

The intended use of the device is for esthetic purposes only. For this reason, performance Data was not pursued.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Innovation MediTech, GmbH
C/O Ms. Elizabeth Wolfsen
Regulatory Affairs Specialist
Vident
3150 East Birch Street
BREA CA 92821

Re: K123761
Trade/Device Name: Vita Enamic® Stains
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: December 1, 2012
Received: December 12, 2012

Dear Ms. Wolfsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A Dreve Company

Indications for Use

510(k) Number (if known):

Device Name: Vita Enamic® Stains
Indications for Use:

Vita Enamic® Stains are indicated for shade customization and characterization of the surface of dental restorations made of hybrid ceramic-resin and resin materials.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA Mary S. Runner -S
2013.02.27
12:10:15 -05'00'

(Division Sign Off)
Division of Dental Infection Control and General Hospital Devices

510(k) Number: K123761

Prescription Use ___X___ OR Over-The-Counter Use_____
(Par. 21 CFR 801.109

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